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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,639	05/16/2001	Nissim Darvish	20066.73	3851

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EXAMINER

EVANSKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/720,639	Applicant(s) DARVISH ET AL.	
	Examiner George R Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-204 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-15, 50-54, 57-64, 151, 155, 161-164, 166-168 and 172-177 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 55 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 16-49, 65-150, 152-154, 156-160, 165, 169-171, and 178-204 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected embodiments, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/13/04.

Applicant's election with traverse of the election of species in the reply filed on 12/13/04 is acknowledged. The traversal is on the ground(s) that all embodiments are sufficiently closely related that searching and consideration will be substantially coextensive. This is not found persuasive because the search is not coextensive due to the different claimed limitations and because the claims must be considered separately since every non-elected claim limitation is different than the elected claim limitations.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8, 9, 50-54, 57, 58, 151, 155, 164, 166, 172, 173, and 176 are rejected under 35 U.S.C. 102(e) as being anticipated by Mouchawar et al (5906633).

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Mouchawar applies a signal that is capable of meeting the intended use recitations of pacing the heart (claim 1) and inherently performs a method for pacing (claim 50), modifying a characteristic of pulsatile blood flow (claim 151), and increasing a contractility by 10% (claim 155), because he provides a signal (40 Volts, 10-20 ms--column 9) that will/can cause an action potential of the heart and is similar to the applicants pulse length. Although Mouchawar calls his signal a "cardioversion" signal, his signal will/can still cause an action potential and will still pace the heart and will not cause cardioversion in a larger sized heart. In addition, the particular type of heart (human, whale, mouse, etc) and the signal level needed for pacing and cardioversion have not been claimed, only that the signal is 8 ms and is a "pace" signal. Also, Mouchawar shows in figure 8 the sensor, 406, for determining when to apply/modify the signal for the heart for enhancement, such as during arrhythmias. In addition, figure 8 shows the H-bridge applying the signal to the heart and it is inherent that electrodes are therefore used.

Claims 1-3, 5, 8-13, 50-52, 54, 57-62, 151, 155, 161, 164, 166, 168, 172, 173, and 175-177 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll et al (5978703).

Kroll applies a signal that is capable of meeting the intended use recitations of pacing the heart (claim 1) and inherently performs a method for pacing (claim 50), modifying a characteristic of pulsatile blood flow (claim 151), and increasing a contractility by 10% (claim 155), because he provides a signal (10-200 Volts [column 5, lines 10-19], 1-5 ms pulse width [figure 4], in a train of 10 pulses with 500 ms between pulses [figure 4, column 4, and/or column 5, line 59]) that will/can cause an action potential of the heart, therefore the signal will "pace" the heart. In addition, the particular type of heart (human, whale, mouse, etc) and the signal level needed for pacing and cardioversion have not been claimed, only that the signal is at least 8 ms

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and is a “pace” signal. Also, Kroll discloses the use of sensors, 44 or 46, 406, for determining when to apply/modify the signal for the heart for enhancement, such as during arrhythmias (column 5, line 63 and column 6, lines 10-19). In addition, since his signal and electrodes will be used for increasing pulsatile/blood flow, they will inherently engender a redistribution of cardiac muscle mass.

Claims 1-5, 8-10, 12-15, 50-54, 57-59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, and 177 are rejected under 35 U.S.C. 102(e) as being anticipated by Mower (6141586).

Mower applies a signal that is used for pacing the heart (claim 1) and performs a method for pacing (claim 50), and inherently modifies a characteristic of pulsatile blood flow (claim 151), and increases a contractility by 10% (claim 155), because he provides a signal (8 ms [column 5, lines 10-19] or over 200 ms post heartbeat [column 5, line 5 and throughout] and 20 Volts) that will cause an action potential of the heart and is of the same or similar pulse duration and characteristic as the applicant’s pulse. In addition, the particular type of heart (human, whale, mouse, etc) and the signal level needed for pacing and cardioversion have not been claimed, only that the signal is at least 8 ms and is a “pace” signal. Also, Mower discloses the use of sensors, column 7, lines 20-35, for determining when to apply/modify the signal for the heart for enhancement. In addition, since his signal and electrodes will be used for increasing cardiac contraction and pulsatile/blood flow, they will inherently engender a redistribution of cardiac muscle mass. For claim 162, the signals will be applied “according to a predetermined time sequence” since the signals were programmed to be delivered “cyclically paced either on the same or similar time protocol or independently” (column 7, line 67).

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Claims 1-5, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ben-Haim et al (WO 97/25098).

Ben-Haim applies a signal that is capable of meeting the intended use recitations of pacing the heart (claim 1) because he provides a signal (10-140 ms duration [page 19, line 5] and less than 20 mA [page 27, line 3]) that will/can cause an action potential of the heart, therefore the signal will “pace” the heart. In addition, the particular type of heart (human, whale, mouse, etc) and the signal level needed for pacing and cardioversion have not been claimed, only that the signal is at least 8 ms and is a “pace” signal.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 168 and 177 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mouchawar et al. Mouchawar teaches in

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column 5, line 53, the use of leads within the heart (endocardial leads) for the H-bridge and similar leads throughout in reference to the H-bridge. In addition, since his signal and electrodes will be used for increasing pulsatile/blood flow, they will inherently engender a redistribution of cardiac muscle mass.

In the alternative, Mouchawar discloses the claimed invention except for the endocardial electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable device as taught by Mouchawar, with endocardial electrodes since it was known in the art that implantable stimulation devices use endocardial electrodes to allow the direct stimulation of the heart with lower energies.

Claim 167 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll et al. Kroll states that he uses his system in a pacemaker, shows in column 5 that pacemakers use lower energy pulses than his extended signals, and only provides his extended signal for responsive to a demand for enhancement and therefore will apply the pacing signal in the absence of the demand.

In the alternative, Kroll discloses the claimed invention except for applying a lower energy pacing signal in the absence of the enhancement signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method using the extended signal pacemaker as taught by Kroll, with a pacing signal in the absence of the enhancement signal since it was known in the art that pacemakers apply a low energy pacing signal (lower than the energy of Kroll's extended signal) and in the absence of an enhancement signal related to pressure or fibrillation, asystole, tachycardia, etc to provide a low energy signal that can pace the heart over a longer period for bradycardia.

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Claims 163 and 167 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mower. Mower teaches the use of his ventricular extended pacing signal in an atrial pacemaker (column 9) and inherently will be of a smaller duration and lower energy and not rely on the ventricular enhancement signal since regular pacing signals are of a shorter duration, lower energy, and are applied based on atrial needs.

Mower discloses the claimed invention except for the conveying a pacing signal having a shorter duration to a different chamber (claim 163) and in the absence of enhancement, conveying a signal with a lower energy (claim 167). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method using an atrial and ventricular pacemaker as taught by Mower, with conveying a pacing signal having a shorter duration to a the atrial chamber and in the absence of enhancement, conveying a signal with a lower energy since it was known in the art that atrial pacemakers use a pacing signal applied in the atrium having a shorter duration than 8 seconds to provide a pacing signal of low energy to pace the atrium and to apply with signal in the absence of the enhancement signals used in Mower to provide bradycardia support pacing to the atrium when needed.

Claim 174 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mouchawar (or Kroll or Mower).

Mouchawar (or Kroll or Mower) discloses the claimed invention except for the sensing being a monophasic action potential signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensing and stimulation system as taught by Mouchawar (or Kroll or Mower), with the sensing being a monophasic action

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potential signal since it was known in the art that sensing and stimulation systems sense a monophasic action potential signal to determine which portions of the heart are viable.

Allowable Subject Matter

Claims 6, 7, 55, and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

2/13/5

GRE
February 13, 2005

Continuation of Disposition of Claims: Claims withdrawn from consideration are 16-49,65-150,152-154,156-160,165,169-171 and 178-204.